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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/583,280	06/16/2006	Charles L. Sawyer	58086-232451 (2003-279-2)	2639

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EXAMINER	
AEDER, SEAN E	

ART UNIT	PAPER NUMBER
1642	

MAIL DATE	DELIVERY MODE
02/27/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/583,280	SAWYER ET AL.	
	Examiner	Art Unit	
	SEAN E. AEDER	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-19* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1, 3, 5, 7, and 9, drawn to methods of examining the physiological effect of a compound on a cancer cell comprising determining an abnormal level of mRNA encoding a polypeptide of interest in said cancer cell.

Group II, claim(s) 2, 4, 6, 8, and 19, drawn to drawn to methods of examining the physiological effect of a compound on a cancer cell comprising determining an abnormal level of a polypeptide of interest in said cancer cell.

It is noted that the claims of the instant application have been determined to include linking claims. Claim 10 link(s) inventions III-V, as set forth below. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claim 10. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/ are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Group III, claim(s) 11, as specifically drawn to a method of inhibiting growth of hormone refractory prostate cancer cell comprising decreasing the biological function of androgen receptors comprising affecting androgen receptor DNA levels.

Group IV, claim(s) 11, as specifically drawn to a method of inhibiting growth of hormone refractory prostate cancer cell comprising decreasing the biological function of androgen receptors comprising affecting androgen receptor mRNA levels.

Group V, claim(s) 11-16, as specifically drawn to a method of inhibiting growth of hormone refractory prostate cancer cell comprising decreasing the biological function of androgen receptors comprising affecting androgen receptor protein levels.

Group VI, claim(s) 17, drawn to a method for determining if a prostate cancer cell is hormone sensitive or has become hormone refractory comprising determining the level of mRNA in a cell that encodes the androgen receptor polypeptide and comparing that level to the level of mRNA encoding androgen receptor polypeptide in a hormone sensitive prostate cancer cell..

Group VII, claim(s) 18, drawn to a method for determining if a prostate cancer cell is hormone sensitive or has become hormone refractory comprising determining the level of androgen receptor polypeptide in a selected cell and comparing that level to the level of androgen receptor polypeptide in a hormone sensitive prostate cancer cell.

The inventions listed as groups I-VII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: groups I-VII encompass different special technical features as identified in the groupings above. The inventions listed above do not relate to a single general inventive concept under PCT Rule 13.1 because under unity of invention between different *categories* of inventions unity of invention will only be found to exist if specific combinations of inventions are present.

A national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept. When claims to different categories are present in the application, the claims will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories: (1) A product and a process specially adapted for the manufacture of said product; or (2) A product and a process of use of said product; or (3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or (4) A process and an apparatus or means specifically designed for carrying out the said process; or (5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process. The allowed combinations do not include multiple products and multiple methods of using said products, as claimed in the instant application.

If multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application is considered as the main invention in the claims, see PCT article 17(3) (a) and 1.476 (c), 37 C.F.R. 1.475(b) and (d). Group I is the main invention. After that, all other products and methods are broken out as separate groups (see 37 CFR 1.475(d).).

In the instant case, the first invention of the first category mentioned consists of methods of examining the physiological effect of a compound on a cancer cell comprising determining an abnormal level of mRNA encoding a polypeptide of interest in said cancer cell. The remaining claims are drawn to distinct methods which use distinct reagents, have distinct response variables, and/or have distinct objectives. Therefore, methods of examining the physiological effect of a compound on a cancer cell comprising determining an abnormal level of mRNA encoding a polypeptide of interest in said cancer cell are considered the "main invention" and the remaining methods have been properly restricted into separate groups.

Species

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Group V is generic to a plurality of disclosed **patentably distinct species of methods of decreasing the biological function of androgen receptors comprising affecting androgen receptor protein levels** comprising the following: methods wherein androgen receptor protein level is decreased through modulation of signal transduction pathways by targeting EGF receptors that crosstalk to the androgen receptor; methods wherein the androgen receptor protein level is decreased by induction of cellular degradation pathways; methods wherein the androgen receptor protein level is decreased by dissociating the androgen receptor from heat shock proteins that maintain the androgen receptor integrity; methods wherein the androgen receptor protein level is decreased by using androgen receptor antisense or mRNA knockdown technology; methods wherein the androgen receptor protein level is decreased by modifying the polynucleotide sequence of the androgen receptor; methods wherein the androgen receptor protein level is decreased by modifying the polypeptide sequence of the androgen receptor; methods wherein the androgen receptor protein level is decreased by phosphorylation of the androgen receptor; methods wherein the androgen receptor protein level is decreased by acetylation of the androgen receptor; methods wherein the androgen receptor protein level is decreased by ubiquitination of the androgen receptor; and methods wherein the androgen receptor protein level is decreased by sumolation of the androgen receptor. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: The methods of the above species differ at least in objectives, method steps, reagents, response variables, and/or criteria for success such that one species could not be interchanged with the other. Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species,

including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SEAN E. AEDER whose telephone number is (571)272-8787. The examiner can normally be reached on M-F: 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sean E Aeder/
Primary Examiner, Art Unit 1642